UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/542,120 | 02/27/2006 | Marielle P.K.J Engelen | 140/1643US | 8717 |

22822 7590 11/12/2009

LEWIS, RICE & FINGERSH, LC
ATTN: BOX IP DEPT.
500 NORTH BROADWAY
SUITE 2000
ST LOUIS, MO 63102

| EXAMINER | |
|---|---|
| PACKARD, BENJAMIN J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1612 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/12/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDEPT@LEWISRICE.COM
KDAMMAN@LEWISRICE.COM

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/542,120 | ENGELEN ET AL. | |
| | Examiner | Art Unit | |
| | Benjamin Packard | 1612 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Applicants' arguments, filed 8/28/09, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Objections***

Applicant's response filed 08/28/09 states at pg 12 that Examiner failed to address pending claims 14 and 15, which Applicants presumed to be allowable.

Examiner notes the claim set filed 12/22/08 was the last claim set filed before the last Office Action, mailed 04/28/09. The claim set filed 12/22/08 only contains 13 claims, with claims 10, 12 and 13 under examination, as noted in Applicant's Arguments dated 12/22/08 (see pg 5 first paragraph). Thus, where claims are not presented for Examination, they cannot be examined.

As such, claims 14 and 15 are objected to because of the following informalities:

Claims 14 and 15 were never presented and should have properly been labeled "new". Applicants are requested to apply the correct claim status identifiers to these claims in the future.

***Claim Rejections - 35 USC § 112 – New matter***

**Claims 10, 12-13, and 16-20** stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement where

Applicants amended the transition phrase from "comprising" to "consisting essentially of".

Applicants assert the descriptive material set forth the specification defines what the basic and novel characteristics of the composition are. As such, "consisting essentially of" is limited to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. Applicants then assert the basic invention relates to administration of the active ingredients at up to 3 grams per dose with a daily dose range of about 9-20 grams for an adult.

Examiner disagrees. The question is not what the basic and novel characteristic is, but whether Applicants have written support for limiting the composition to only the materials or steps and those that do not materially affect the basic and novel characteristics. The instant specification presents working examples which limit the composition administered to glutamate, but such examples do not suggest that Applicants had written support for limiting the composition in such a way as now claimed.

***Claim Rejections - 35 USC § 103***

**Claims 10 and 12-20** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pouw et al (American Journal of Respiratory Critical Care Medicine, vol 158, 1998, 797-801, see Applicants IDS dated 7/11/2005) in view of Meiji Milk Prod Co Ltd (EP 0873754, see Applicants IDS dated 7/11/2005).

Applicants assert that prior to the disclosure of the compositions of Applicant's application low doses of glutamate would have been expected to largely be extracted by the splanchnic area, resulting in a very small increase in systemic plasma which would not raise the skeletal muscle concentration very much. Applicants also assert Meiji, while incorporated in glutamic acid, does not have to incorporate the same, thus showing the amino acids are not essential and the art effectively teaches away where the only active is glutamic acid. Second, Applicants assert the glutamic acid is present in extremely small molar ratios, which would result in no significant increase in glutamic acid in the skeletal muscles. Third, Applicants assert Meiji teaches compositions which contain other essential amino acids not present in Applicant's claims or essential in Applicant's invention.

Examiner disagrees. First, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the dosage amount) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). While new claims 19 and 20 discuss dosages, they are not directed to a dosage form, but simply the total dosage (claim 19) and dividing the dosages to forms of up to 3 grams (claim 20). Thus, where any dosage amount is administered up to the required daily level, the claim limitations appear to be met.

Further, Applicants assertion that Meiji does not require glutamic acid and that it teaches away in not well founded. Meiji was cited for the teaching that various amino acids could be administered to a patient, thereby increasing the amino content in the blood supply. While Meiji does not focus exclusively on glutamic acid and/or its precursors, such is not required where only the general teaching was cited. Instead, Examiner cited Pouw et al for the teaching that glutamic acid was a key amino acid in patients with COPD. Therefore, the skilled artisan, when trying to increase the deficient levels of glutamic acid as taught by Pouw et al, would use known methods of increasing amino acids, such as disclosed in Meiji.

Second, Applicants own statement that the low levels of glutamic acid do not result in a significant increase in glutamic acid in the skeletal muscles appears to suggest that there is at least some increase of glutamic acid in the skeletal muscles. Where the instant claims are directed to treating COPD and skeletal muscle fatigue related thereto, any increase in glutamic acid in the skeletal muscles would reasonably be expected to provide some therapeutic effect. Additionally, the skilled artisan, when trying to raise the glutamic acid as suggested by the primary reference, would optimize the dosage of the secondary reference, raising the amino acid content sufficient to produce the desired effect, i.e. raise the glutamic acid levels.

Finally, the instant claims, even the new claims, are not limited to compositions consisting of glutamate, even though claims 16 states "wherein said composition contains no other active components besides said glutamate and said precursor of said glutamate." Instead, Examiner notes claim 16 is directed to a method of treatment which

"comprises" administering the claimed composition. Where the transition phrase "comprising" precedes the definition of the composition, additional compositions may also be present in the treatment. Thus, the composition of Meiji can be viewed as a composition of glutamic acid and a composition of other amino acids, mixed into one. Note, even if the method were limited to only administration of glutamic acid and its precursor, Examiner notes Meiji was cited for the teaching that an amino acid supplement may be used to increase the amino acid in the blood serum. Thus, when reading Pouw et al, the skilled artisan would design an amino acid supplement to treat the deficiency of glutamate in patients with COPD.

***Conclusion***

No claims allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612